IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

Canopy Growth Corporation, *Plaintiff*, v. GW Pharma Limited and GW Research Limited, *Defendants*.	)	Civil Action No. 6:20-cv-01180-ADA **JURY TRIAL DEMANDED**

PLAINTIFF'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

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Canopy Growth Corporation ("Canopy" or "Plaintiff") submits this responsive claim construction brief to address the disputed claim limitation "CO_2 in liquefied form under subcritical pressure and temperature conditions," recited in both asserted independent claims of U.S. Patent No. 10,870,632 ("the '632 Patent"). GW's proposed construction improperly seeks to add a new limitation into the claim language in an apparent attempt to evade infringement.[1] To do so, GW contradicts plain and ordinary meaning, improperly reads out subcritical embodiments expressly disclosed in the specification, and disregards the relevant prosecution history. GW's attempt to add new limiting language into the claims should be rejected, and the disputed limitation should be given its plain and ordinary meaning.

I. FACTUAL AND PROCEDURAL BACKGROUND

Canopy accuses GW Pharma Ltd. ("GWP") and GW Research Limited ("GWR") (collectively, "GW" or "Defendants") of infringing Claims 1-3, 5-16, and 18-25 of the '632 Patent. The '632 Patent generally relates to a process for producing an extract containing tetrahydrocannabinol (THC), CBD, and optionally the carboxylic acids thereof from *cannabis* plant materials. '632 Patent at 1:23-26. For example, independent Claim 1 recites:

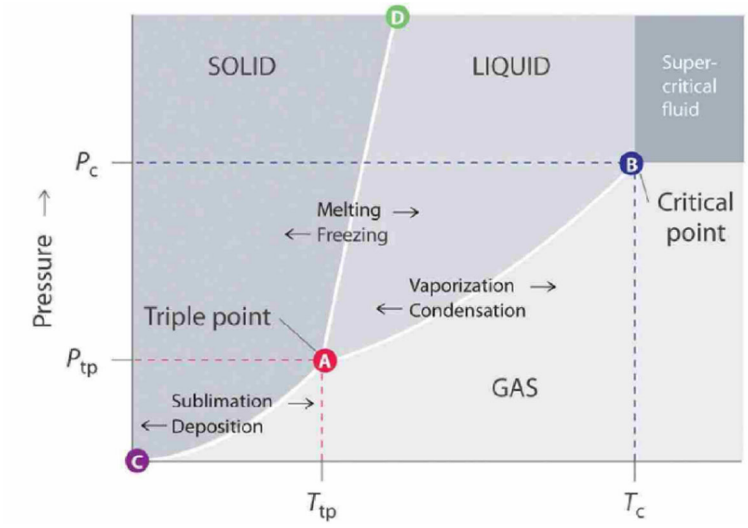
> 1. A process for producing an extract containing Tetrahydrocannabinol (THC) and/or cannabidiol (CBD), and optionally the carboxylic acids thereof, from a *cannabis* plant material or a primary extract thereof, said process comprising:
>
> (1) subjecting the *cannabis* plant material or primary extract thereof to ***CO_2 in liquefied form under subcritical pressure and temperature conditions*** to extract cannabinoid components; and
>
> (2) reducing the pressure and/or temperature to separate tetrahydrocannabinol and/or cannabidiol, and optionally the carboxylic acids thereof, from the CO_2.

[1] GW's suggestion that Canopy somehow seeks to broaden the claims only after receiving some of GW's produced documents is an unfounded attempt to distract from the merits. *See* Dkt. 27 at 1. GW identified this term for construction—not Canopy—and Canopy did not disclaim any claim scope in its infringement contentions.

'632 Patent, Claim 1 (emphasis added). The parties dispute the limitation "CO_2 in liquefied form under subcritical pressure and temperature conditions," recited in the extraction step, emphasized above. Independent Claim 14 also recites this disputed limitation in its extraction step. '632 Patent, Claim 14 ("subjecting the decarboxylated *cannabis* plant material or primary extract thereof to ***CO_2 in liquefied form under subcritical pressure and temperature conditions*** to extract cannabinoid components").

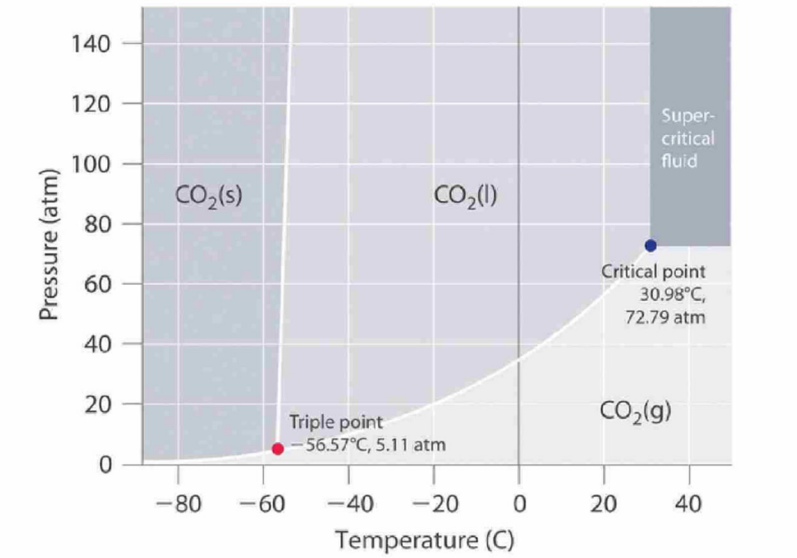
Carbon dioxide (CO_2), may exist under subcritical or supercritical conditions. *Accord* Dkt. 27 at 2 ("Supercritical and Subcritical CO_2"). Under subcritical pressure and temperature conditions, CO_2 may exist as a solid, liquid, or gas. Ex. B, Canopy_000001121, at 1121. Under supercritical conditions, CO_2 has characteristics of both a liquid and a gas. *See, e.g.*, Ex. A, Canopy_000001330, at 1331 ("[A] supercritical fluid is essentially a fluid with gas-like densities and viscosities but it cannot be compressed, thus behaving more like a liquid."). Supercritical conditions are characterized by both the temperature above the critical temperature, and the pressure above the critical pressure for that substance. *Id.*; Ex. B, Canopy_000001121, at 1121.

A generic phase diagram depicting physical states of a substance under different pressure and temperature conditions is depicted below.



Ex. B, Canopy_000001121, at 1121. As depicted in this phase diagram, supercritical conditions exist in the upper right-hand corner, labeled "supercritical fluid," where both the temperature and the pressure are above the critical point (B). *Id.* The rest of the diagram is characterized by subcritical conditions, where the substance may be in the solid, liquid, or gas phases. *Id.*

Every substance has a critical temperature and a critical pressure, and therefore its own specific version of the generic phase diagram depicted above. For CO_2, the critical temperature (T_c) is 31ºC and the critical pressure (P_c) is 73.8 bar (72.8 atm). *Id.* at 1125; *accord* Dkt. 27 at 2. The phase diagram for CO_2 is reproduced below:



Ex. B, Canopy_000001121, at 1125. Again, as depicted above, supercritical conditions for CO_2 are in the upper right-hand corner, labeled "supercritical fluid," where both the temperature and the pressure are above the critical point for CO_2. *Id.* The rest of the diagram discloses subcritical conditions, which result in the solid ("CO_2(s)"), liquid ("CO_2(l)"), and gas ("CO_2(g)") phases. *Id.*

II. APPLICABLE LAW

The words of a patent claim "are generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005).[2] "There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012).

III. AGREED CLAIM TERM

The parties agree on the following construction to correct a typographical error in certain dependent claims:

Term	Construction
"sequiterpenes" (Claims 8, 21)	"sesquiterpenes"

Dkt. 27 at 6 n.3. Canopy requests the Court enter this agreed construction.

IV. DISPUTED CLAIM TERM

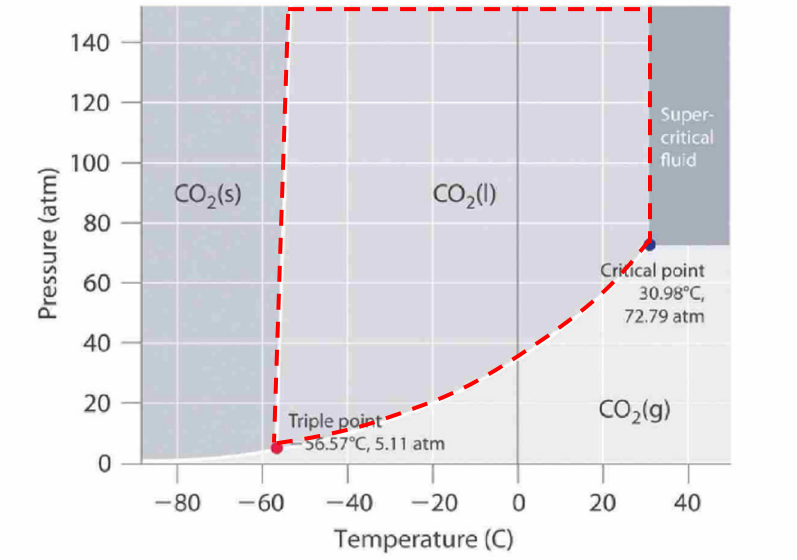
The parties dispute the construction of "CO_2 in liquefied form under subcritical pressure and temperature conditions," recited in independent Claims 1 and 14. The parties' proposed constructions are below[3]:

Plaintiff's Proposed Construction	Defendants' Proposed Construction
Plain and Ordinary Meaning	"CO_2 in liquefied form under **both** subcritical pressure and temperature conditions"

As discussed above, CO_2 may exist under subcritical conditions or supercritical conditions. *See supra* Section I. Under subcritical conditions, CO_2 may exist as a solid, liquid, or gas. *See id.* Thus, the plain and ordinary meaning of "CO_2 in *liquefied form* under *subcritical* pressure and

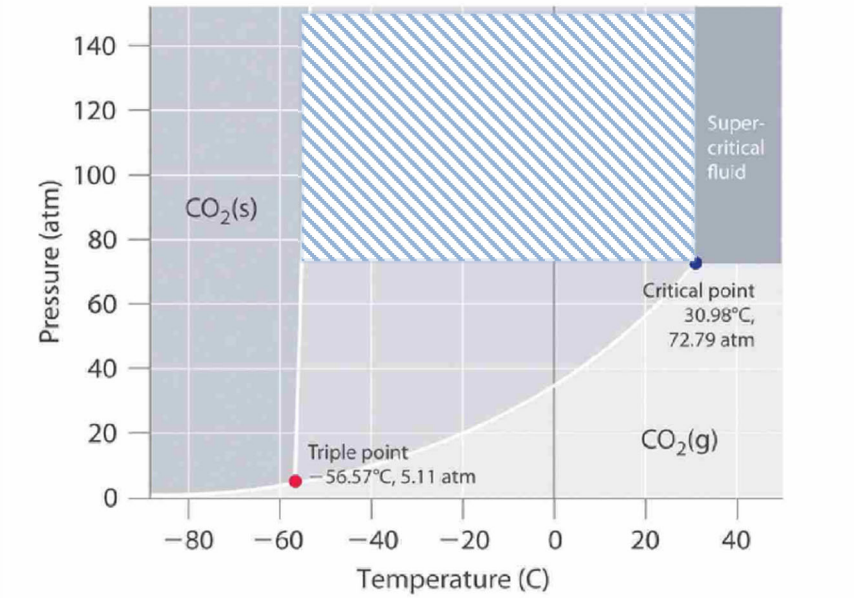
[2] All internal citations and quotations are omitted unless otherwise indicated.
[3] Differences between GW's proposed construction and the disputed claim limitation are indicated in bold and underline.

temperature *conditions*" encompasses the portion of the phase diagram for CO_2 bound by the dashed lines below ("CO_2(l)"):



See Ex. B, Canopy_000001121, at 1125 (dashed lines added).

The parties' dispute centers on whether "CO_2 in liquefied form under subcritical pressure and temperature conditions" includes all liquid CO_2 under subcritical pressure and temperature conditions, or whether, as GW proposes, the word "both" should be added to the claims such that the claims include only liquid CO_2 where "both" temperature is below the critical temperature (T_c) and pressure is below the critical pressure (P_c). In other words, the parties dispute whether the claim limitation at issue encompasses the portion of the liquid phase indicated in striped shading below (which GW proposes should be excluded):



Ex. B, Canopy_000001121, at 1125 (shading added). GW's proposed narrowing improperly deviates from the ordinary meaning of the claim without the requisite justification. As demonstrated by the claims' plain language, embodiments expressly disclosed in the specification that GW improperly would read out, the applicant's arguments distinguishing prior art in the prosecution history, and the extrinsic evidence, all discussed below, the disputed claim limitation encompasses the full range of subcritical pressure and temperature conditions for liquefied CO_2, and GW's proposed construction attempting to narrow this range should be rejected.

A. GW's Proposed Construction Contradicts Plain and Ordinary Meaning.

There is a "heavy presumption that a claim term carries its ordinary and customary meaning." *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002); *see also Phillips*, 415 F.3d at 1312 ("We have frequently stated that the words of a claim are generally given their ordinary and customary meaning."). "There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution."

Thorner, 669 F.3d at 1365. Otherwise, "[t]he patentee is free to choose a broad term and expect to obtain the full scope of its plain and ordinary meaning." *Id*. at 1367.

Canopy seeks the plain and ordinary meaning of "CO_2 in liquefied form under subcritical pressure and temperature conditions." GW's construction seeks to add the word "both" to the claims, improperly narrowing the subcritical conditions of liquefied CO_2 to only those in which "both" pressure is below the critical pressure (P_c) and temperature is below the critical temperature (T_c). GW ignores that the claims recite "subcritical pressure and temperature *conditions*," and not just "subcritical pressure and temperature." As explained further below, subcritical pressure and temperature "conditions" are achieved by having one or both of pressure and temperature below their respective critical points (in other words, not supercritical conditions), and are not limited to "*both* subcritical pressure and temperature," as GW proposes. *See, e.g.*, '632 Patent, at 6:3-12. A person of ordinary skill in the art (POSITA) would have understood the claims to encompass the full range of liquefied CO_2 under subcritical pressure and temperature *conditions*, as supported by the plain language of the claims, express embodiments disclosed in the specification, applicant's arguments distinguishing the prior art in the prosecution history, and extrinsic evidence addressed below. GW's proposed narrowing contradicts the plain and ordinary meaning of the claim without establishing the requisite justification in the form of either lexicography or disclaimer. *See Thorner*, 669 F.3d at 1365.

B. The Plain Language of the Claims Does Not Support GW's Construction.

GW's attempt to add a new limitation into the claims ("both") is unsupported by the plain language of the claims, and contradicts their plain and ordinary meaning and the intrinsic record. *See Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1375 (Fed. Cir. 2004) ("[W]e have repeatedly declined to rewrite unambiguous claim language . . ."). Claims 1 and 14 recite "CO_2 in

liquefied form under subcritical pressure and temperature *conditions*." The claims do not recite under "subcritical pressure and temperature," let alone "both" as GW proposes:

Recited Claim Limitation	GW's Proposed Interpretation
"CO_2 in liquefied form under subcritical pressure and temperature conditions"	"CO_2 in liquefied form under **both** subcritical pressure and temperature ~~**conditions**~~"

The recited "conditions" are subcritical because *both* pressure and temperature are not *above* the critical point (in other words, the conditions are not supercritical). *See, e.g.*, '632 Patent at 5:10-20, 6:3-12 (expressly disclosing subcritical embodiments in which temperature is below the critical temperature and pressure is *above* the critical pressure, and contrasting to embodiments under supercritical conditions); Ex. C, '632 FH, 4/20/20 OA Resp., at 11-12 (Canopy_000000236-37) (distinguishing prior art by contrasting subcritical conditions with supercritical conditions); *id*., 6/26/20 OA Resp., at 8 (Canopy_000000216) (similar); *id*., 8/28/20 OA Resp., at 7-8 (Canopy_000000153-54) (similar). As the intrinsic record makes clear, the pressure and temperature conditions recited in the claims are "subcritical" because one or both of pressure and temperature are below their respective critical points. *See id.*

GW's overemphasis on two words in isolation—"and" and the fact that "conditions" is plural—ignores the full context of the claim language and is inconsistent with express embodiments in the specification, which discloses "subcritical" embodiments in which temperature is below the critical point and pressure is *above* the critical point. *See, e.g.*, '632 Patent at 5:10-20, 6:10-12. Moreover, the claims' use of the plural "conditions" is merely consistent with common parlance, and reflects that pressure and temperature conditions determine the phase of CO_2. *See* Ex. B, Canopy_000001121, at 1125. For example, the specification consistently uses the plural "conditions," even when referring to conditions for only one of pressure or temperature. *See, e.g.*, '632 Patent at 7:49 ("subcritical conditions in terms of

pressure"), 10:31-33 (describing "pressure conditions" for separation).[4] And during prosecution, applicant characterized the disputed limitation interchangeably as "subcritical conditions of temperature and pressure," which contradicts GW's proposed interpretation. *See, e.g.*, Ex. C, '632 FH, 4/20/20 OA Resp., at 11-12 (Canopy_000000236-37); *id.*, 6/26/20 OA Resp., at 7-8 (Canopy_000000215-16) (similar). Thus the use of the plural "conditions" does *not* signify that "both" pressure and temperature must be below their critical points, as GW alleges.

This plain meaning is further supported by dependent Claims 3-5 and 16-18, which depend from Claims 1 and 14. Dependent Claims 3-5 and 16-18 recite either specific pressures below the critical pressure (P_c) or specific temperatures below the critical temperature (T_c) for the extracting step. **None** of the claims, whether independent or dependent, requires "both" a pressure below the critical pressure and a temperature below the critical temperature, as GW attempts to read into all claims. Thus, nothing in the plain language of the claims justifies departing from their plain and ordinary meaning to narrow the claims as GW proposes.

C. GW's Proposed Construction Improperly Reads out Express Subcritical Embodiments from the Specification.

GW's proposed construction improperly reads out express subcritical embodiments described in the specification, in which conditions with pressures *above* the critical pressure (P_c) and temperatures below the critical temperature (T_c) are deemed subcritical.

The specification discloses embodiments for the pressure and temperature conditions of CO_2 extraction under (1) supercritical conditions and (2) subcritical conditions. In at least two separate instances, the specification discloses an express embodiment for extraction under *subcritical* conditions in which the temperature is below the critical temperature and the pressure

[4] Since both parties appear to agree that certain typographical errors in the specification refer to "subcritical," for ease of reference and the Court's convenience, Canopy corrects these typographical errors in all quotations unless otherwise indicated.

is *above* the critical pressure—precisely the embodiment GW seeks to read out from the claims. First, the specification discloses, "[i]n the ***subcritical range***, in contrast, a temperature of approx. 20ºC to 30ºC and a ***supercritical pressure*** of approx. 100 bar to 350 bar are used." '632 Patent at 6:10-12. The specification contrasts these subcritical conditions from supercritical conditions, in which both temperature and pressure are above the critical point. *Id*. at 6:3-12 (describing extraction under supercritical conditions before disclosing, "in contrast," the subcritical conditions in which temperature is below the critical temperature and pressure is *above* the critical pressure).

Second, the specification again discloses embodiments where extraction is performed under supercritical conditions and under subcritical conditions, in the passage below, also cited by GW:

> In accordance with the invention, a primary extract containing tetrahydrocannabinol, cannabidiol, and optionally the carboxylic acids thereof, is obtained from *cannabis* plant material in that the dried plant material is comminuted, the plant material is extracted with the aid of CO_2 ***under supercritical pressure and temperature conditions at a temperature in the range of approx. 31°C to 80°C and at a pressure in the range of approx. 75 bar to 500 bar, or in the subcritical range at a temperature of approx. 20°C to 30°C and a supercritical pressure of approx. 100 bar to 350 bar; or extracted under subcritical pressure and temperature conditions***; and the obtained primary extract is separated under subcritical conditions, or under conditions that are subcritical in terms of pressure and supercritical in terms of temperature.

'632 Patent at 5:6-20 (emphasis added). Here, the specification expressly describes both a specific example of subcritical conditions ("or in the subcritical range at a temperature of approx. 20ºC to 30ºC and a supercritical pressure of approx. 100 bar to 350 bar") and a broad catch-all embodiment of subcritical conditions ("or extracted under subcritical pressure and temperature conditions"). *See id.* GW incorrectly argues this passage discloses three alternative embodiments, when in fact the second embodiment (describing specific subcritical conditions) is a subset of the broader third

embodiment (describing subcritical conditions more generally).[5] The fact that the specification describes both embodiments as "subcritical" plainly contradicts GW's argument. *Id*. Moreover, the disclosure at 6:3-12 described above further undercuts GW's argument, because the same specific subcritical embodiment is again expressly disclosed, and *expressly contrasted only with supercritical conditions*, not with the broader embodiment for subcritical conditions:

> The ***extraction process*** of the invention preferably operates in the ***supercritical range*** at a temperature of approx. 31ºC to 80ºC and a pressure of approx. 75 bar to 500 bar, in particular at a temperature of approx. 45ºC to 65ºC and a pressure of approx. 100 bar to 350 bar, preferably at a temperature of approx. 60ºC and a pressure of approx. 250 bar.
>
> In the ***subcritical range, in contrast, a temperature of approx. 20ºC to 30ºC and a supercritical pressure of approx. 100 bar to 350 bar*** are used.

Id. at 6:3-12 (emphasis added).

Because GW's proposed construction would improperly read out the express embodiment of subcritical conditions where temperature is below the critical temperature (20ºC to 30ºC) and pressure is *above* the critical pressure (100 bar to 350 bar)—described twice in the specification—it should be rejected on this basis alone. *See, e.g*., *Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1583 (Fed. Cir. 1996) (recognizing that reading out an embodiment expressly disclosed in the specification is "rarely, if ever, correct").

GW otherwise points to two exemplary embodiments that relate to the *separating* step, which is the step in which pressure and/or temperature are reduced:

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[5] To attempt to argue that the specific subcritical conditions embodiment is somehow a distinct and wholly unrelated alternative to the broader, catchall subcritical conditions embodiment rather than a subset of it, GW relies solely on numerical notations of [1], [2], and [3] that it *added*, and that do *not* appear in the patent. *See* Dkt. 27 at 3, 7. Again, the specification itself belies GW's argument by deeming both embodiments "subcritical," and when later repeating the specific subcritical conditions embodiment, contrasting it only with supercritical conditions. '632 Patent at 5:6-20, 6:3-12.

> The obtained extract is ***separated out*** under pressure and temperature conditions subcritical for CO_2, ***preferably*** at approx. 55 bar and approx. 25ºC.
>
> [I]n the second and third separating vessels, ***where Δ^8-THC and Δ^9-THC are separated out***, conditions subcritical for CO_2 in terms of pressure and temperature are to prevail, in the second separating vessel ***preferably*** 60 bar and 30ºC, in the third separating vessel ***preferably*** 55 bar and 25ºC.

Dkt. 27 at 8 (quoting '632 Patent, at 7:22-24, 7:51-57) (emphasis added). As the word "preferably" denotes, these are merely exemplary embodiments and not meant to limit the full range of the claimed subcritical pressure and temperature conditions. *See, e.g.*, *Whetstone Elecs., LLC v. Xerox Corp.*, No. 6:10-cv-278, 2011 WL 3510750, at *6 (E.D. Tex. Aug. 10, 2011) (recognizing that use of the word "preferably" in the specification clearly indicates merely a preferred embodiment, and that "limiting the scope of the claim language based on this statement would be improper"). In any event, these embodiments relate to the *separation* step, not the *extraction* step in which the disputed claim limitation is recited. *See* '632 Patent, Claims 1, 14.

GW thus fails to establish any lexicography or "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope," sufficient to justify departing from plain and ordinary meaning. *See Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1334 (Fed. Cir. 2009) (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 229 F.3d 1313, 1325 (Fed. Cir. 2002)); *Thorner*, 669 F.3d at 1365-66. Rather, GW's proposed construction would improperly read out an express subcritical embodiment disclosed in the specification. Accordingly, GW's proposed construction should be rejected.

D. The Prosecution History Supports Plain and Ordinary Meaning.

GW devotes the majority of its brief to the prosecution history, arguing that Canopy disclaimed from its claim scope "CO_2 in liquefied form under subcritical pressure and temperature conditions" where pressure and temperature are not "both" below their respective critical points.

See Dkt. 27 at 9-13. GW not only fails to demonstrate any clear and unmistakable disavowal, but it relies on amendments to claims that were *canceled entirely*, and therefore are less probative of the scope of the issued claims. Further, during prosecution of the rewritten and relevant claims—the ones that ultimately led to the issued claims before the Court—applicant consistently distinguished "CO_2 in liquefied form under subcritical pressure and temperature conditions" from *supercritical* CO_2 in the prior art, further supporting that ordinary meaning encompasses the full range of pressure and temperature conditions for CO_2 in the liquid phase of subcritical conditions, as opposed to CO_2 as a supercritical fluid under supercritical conditions.

1. GW Fails to Establish Clear and Unmistakable Disclaimer Required to Justify Departing from Plain and Ordinary Meaning.

"[F]or prosecution disclaimer to attach, our precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable." *Omega Eng'g, Inc. v. Raytek Corp*., 334 F.3d 1314, 1325-26 (Fed. Cir. 2003). The Federal Circuit has described the standard for disavowal as "exacting," requiring "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Thorner*, 669 F.3d at 1366; *Epistar*, 566 F.3d at 1334 (quoting *Teleflex*, 299 F.3d at 1325). Thus disclaimer does not apply "[w]here the alleged disavowal is ambiguous, or even amenable to multiple reasonable interpretations." *Avid Tech., Inc. v. Harmonic, Inc*., 812 F.3d 1040, 1045 (Fed. Cir. 2016). Further, prosecution history disclaimer rarely justifies reading out an embodiment. *SEB S.A. v. Montgomery Ward & Co., Inc*., 594 F.3d 1360, 1369-71 (Fed. Cir. 2010); *Amgen Inc. v. Hoechst Marion Roussel, Inc*., 314 F.3d 1313, 1349 (Fed. Cir. 2003). The party seeking to invoke disclaimer bears the burden to prove disclaimer. *Mass. Inst. of Tech. v. Shire Pharm., Inc*., 839 F.3d 1111, 1119 (Fed. Cir. 2016).

GW alleges that during the prosecution of the '632 Patent and its parent patent, U.S. Patent No. 8,895,078 ("the '078 Patent"), applicant disclaimed claim scope of extraction with liquefied

CO_2 under subcritical pressure and temperature conditions that do not involve "both" pressure below the critical pressure and temperature below the critical temperature. Dkt. 27 at 11-13. GW fails to point to any statement in the prosecution history for either patent that amounts to an express manifestation to exclude any pressure and temperature conditions from the full scope of CO_2 in the liquid phase under subcritical conditions, as required to show disclaimer.

For the '632 Patent, GW relies on claims that were *canceled*, and therefore do not relate to the presently asserted claims before the Court. All portions of the prosecution history relied on by GW pre-date the applicant's April 20, 2020 amendment, where the applicant *canceled* all claims and submitted new claims that do not contain the limitations or amendments that GW attempts to distinguish from the recited limitation in dispute. *Compare* Dkt. 27 at 11-13 *with* Ex. C, '632 FH, 4/20/20 OA Resp., at 7 (Canopy_000000232).

GW otherwise relies on the prosecution of the parent '078 Patent to argue disclaimer, but this patent recites different claims. Dkt. 27 at 9-11. The '078 Patent claims relied on by GW—specifically, the limitations that relate to CO_2 conditions for the extraction—are similar to the claims that were *canceled* in the '632 Patent file history, not those that led to the ultimately issued claims at issue here. *Compare* Dkt. 27 Ex. 4 at 10 (1/3/09 Claims at 2) and Dkt. 27 Ex. 5 ('078 Patent at Claims 1-3) (cited by GW in Dkt. 27 at 9) *with* Ex. C, '632 FH, 4/20/20 OA Resp., at 7.

GW does not demonstrate how any statement or action by applicant with respect to these canceled claims, or claims of a different patent that track the canceled claims, amount to a clear and unmistakable disavowal of the currently asserted claims. *See, e.g.*, *Mass. Institute of Tech.*, 839 F.3d at 1120-22 (discounting allegedly disclaiming statements made during prosecution when made "in the context of different claims" that were ultimately canceled, finding the statements "do not meet the high standard for prosecution disclaimer to attach"); *Ventana Med. Sys., Inc. v.*

Biogenex Labs., Inc., 473 F.3d 1173, 1182-83 (Fed. Cir. 2006) (patentee's arguments to distinguish claims of an earlier, related application reciting different terms did not amount to disclaimer).

Nothing in the prosecution histories of the '632 or '078 Patents meets the "exacting" standard for disavowal or disclaimer—let alone with respect to the new claims that ultimately issued into the claims asserted in this case. GW thus fails to "overcome a heavy presumption that claim terms carry their full ordinary and customary meaning," by showing "the patentee expressly relinquished claim scope" through clear and unmistakable disclaimer. *See Epistar*, 566 F.3d at 1334 (citing *Omega Eng'g*, 334 F.3d at 1323).

2. Applicant Distinguished Subcritical Conditions from Supercritical Conditions During the Relevant Prosecution History, Consistent with Plain and Ordinary Meaning.

On April 20, 2020, the office action response that immediately follows GW's selectively excerpted file history, applicant canceled all pending claims and submitted new claims. Ex. C, '632 FH, 4/20/20 OA Resp., at 7 (Canopy_000000232). As applicant indicated, "[t]his listing of claims will replace all prior versions, and listings, of claims in the application." *Id*. Applicant's new independent claim 35 (now claim 1) recites as follows:

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1 – 35. (Canceled)

36. (New) A process for producing an extract containing Tetrahydrocannabinol (THC) and/or cannabidiol (CBD), and optionally the carboxylic acids thereof, from a cannabis plant material or a primary extract thereof, said process comprising:

(1) subjecting the cannabis plant material or primary extract thereof to CO_2 in liquefied form under subcritical pressure and temperature conditions to extract cannabinoid components; and

(2) reducing the pressure and/or temperature to separate tetrahydrocannabinol and/or cannabidiol, and optionally the carboxylic acids thereof, from the CO_2.

Id. It is this set of claims, not the claims that GW relies on, that ultimately led to the claims at issue in the '632 Patent. Yet GW ignores the prosecution of these claims entirely. *See* Dkt. 27 at 9-13 & Ex. 6.

After applicant canceled its original claims and submitted new claims to the Patent Office, applicant repeatedly and consistently distinguished subcritical conditions from supercritical conditions, consistent with plain and ordinary meaning. First, in its April 20, 2020 response, applicant distinguished the relevant claims from the prior art, and in particular the alleged primary reference Webster, because Webster disclosed extraction solely with CO_2 as a *supercritical* fluid, not CO_2 under subcritical conditions:

> Thus, Webster does not teach to use liquid CO_2 under subcritical conditions of temperature and pressure. In the above paragraph, Webster is describing extraction using CO_2 solely in the form of a **supercritical fluid**. . . . . Nowhere does Webster teach or suggest to use subcritical CO_2 in liquefied form.

Ex. C, '632 FH, 4/20/20 OA Resp., at 12 (Canopy_000000237) (emphasis in original). Applicant similarly distinguished a secondary reference on these grounds. *Id*. (arguing Gregg disclosed "using CO_2 under **supercritical conditions** of at least 500 bar," and teaches away "from using less than 500 bar (see the examples), and more particularly do not provide any teaching or suggestion to use CO_2 in liquefied form under subcritical conditions.") (emphasis in original). Applicant repeated essentially the same arguments in its next office action response. *Id.*, 6/26/20 OA Resp., at 8 (Canopy_000000216).

In the next and last office action response before the examiner allowed the claims, applicant once again distinguished the prior art by contrasting subcritical from supercritical conditions. *Id.*, 8/28/20 OA Resp., at 7-8 (Canopy_000000153-54) ("Examiner appears to argue at page 7 of the Office Action that Applicant's claims read on the supercritical conditions of Webster or that

Webster teaches an adjustment that Applicant's claims would read on. Applicant strongly disagrees."); *see also id*. at 8 ("Applicant disagrees and submits that Webster's supercritical CO_2 does not read on Applicant's claims.") (emphasis in original). Applicant further explained:

> As previously submitted, the sentence in Webster referring to an adjustment (col. 4, ln. 58-60) merely describes that changes in temperature and pressure **of the supercritical fluid** (i.e. above 32ºC and 73 atm) can vary the effective polarity. Webster is still referring to a ***supercritical fluid*** (i.e. one that is under sufficient pressure and heat that it is no longer distinctly liquid or gaseous). Nowhere does Webster teach or suggest to adjust the temperature and pressure to use ***subcritical CO_2 in liquefied form***.

Id. at 8 (Canopy_000000154) (some emphasis in original, some added).

Thus in all three of the office action responses applicant submitted after canceling the claims that GW relies on and submitting new claims, applicant distinguished the claimed CO_2 under subcritical pressure and temperature conditions from *supercritical* conditions in the prior art, after which the examiner allowed the claims. Accordingly, the prosecution history supports the plain and ordinary meaning that the claimed subcritical conditions encompass the full range of subcritical pressure and temperature conditions for liquefied CO_2 that do not result in supercritical CO_2, contrary to GW's proposed construction.

E. The Extrinsic Evidence Supports Plain and Ordinary Meaning.

"[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective date of the patent application." *Phillips*, 415 F.3d at 1313. "The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." *Id*. The plain and ordinary meaning is further supported by extrinsic evidence, which evidences that POSITAs did not and do not understand subcritical conditions as requiring "both" pressure and temperature to be below the critical point.

POSITAs describe subcritical fluid extractions as those encompassing the full subcritical liquid conditions (in other words, not a supercritical fluid). For example, one publication directed to CO_2 extraction of cannabis (the same subject matter of the '632 Patent) describes subcritical CO_2 as CO_2 that is not supercritical, explaining that "[s]ubcritical CO_2 can be achieved by ***either lowering the pressure*** below P_c ***or the temperature*** below T_c." Ex. A, Canopy_000001330, at 1332 (emphasis added). Moreover, POSITAs describe subcritical conditions in contrast to *supercritical* conditions, consistent with plain and ordinary meaning. *See, e.g.*, Ex. D, Canopy_000001272, at 1273 ("The term *subcritical* refers to a liquid at temperatures between the atmospheric boiling point and the critical temperature, *whereas in the supercritical state*, experimental conditions are higher than the critical temperature and pressure.") (emphasis added). GW's proposed construction adding the requirement that "both" pressure be below P_c and temperature be below T_c directly contradicts this plain and ordinary meaning as understood by POSITAs.

In fact, the literature is rife with examples—from the 1990s to the present day—of CO_2 extractions performed under subcritical conditions which would not fall within GW's narrow construction, as shown in Table 1.

Table 1: CO_2 Extractions in Literature Deemed Subcritical Where "Both" Pressure and Temperature are Not Below their Respective Critical Points[6]

Extraction Temperature	Extraction Pressure	Evidence
Below T_c (25ºC)	Above P_c (205 bar)	Dillow, Angela K. et al., Bacterial Inactivation by Using Near- and Supercritical Carbon Dioxide, 96 Proc. Natl. Acad. Sci. USA 10344 (1999) (Ex. E, Canopy_000001105, at 1106-07).
Above T_c (40-45ºC)	Below P_c (900-950 psi or	Stashenko, Elena et al., High-Resolution Gas-Chromatographic Analysis of the Secondary

[6] For reference, the critical temperature (T_c) and critical pressure (P_c), for CO_2 are 31ºC and 73.8 bar (72.8 atm), respectively. Ex. B, Canopy_000001121, at 1125; *accord* Dkt. 27 at 2.

	62-65.5 bar)	Metabolites Obtained by Subcritical-Fluid Extraction from Colombian Rue (*Ruta Graveolens* L.), 43 J. of Biochem. Biophys. Methods 379 (2000) (Ex. F, Canopy_000001301, at 1301-02).
Below T_c (25ºC)	Above P_c (12 MPa or 120 bar)	Rochova, Kristina, Effect of Plant Structure Modification and Natural Convection in Solvent on the Rate of Supercritical Extraction, Universite de La Rochelle (2008) (Ex. G, Canopy_000001126, at 1182, 1212, 1216).
Below T_c (30ºC)	Above P_c (10 and 20 MPa or 100 and 200 bar)	Duval, Johanna, et al., Selective Enrichment in Bioactive Compound from *Kniophofia Uvaria* by Super/Subcritical Fluid Extraction and Centrifugal Partition Chromatography, 1447 J. of Chromatography 26 (2016) (Ex. D, Canopy_000001272, at 1275 (Table 2)).
Below T_c (-60 to -80ºF or -51.1 to -62.2ºC)	Pressures spanning both below and above P_c (500 to 5000 psi or 34.5 to 344.7 bar)	U.S. Patent No. 10,315,129 to Auerbach et al. (Ex. H, Canopy_000001258, at 1:36-38, 1:55-59, 2:9-17).
At T_c (31ºC)	Above P_c (3000 psi or 207 bar)	Shen, Yufeng et al., Online Supercritical Fluid Extraction Mass Spectrometry (SFE-LC-FTMS) for Selective Characterization of Soil Organic Matter, 218 Faraday Discussions 157 (2019) (Ex. I, Canopy_000001285, at 1285, 1289) ("subcritical fluid extraction (SFE)").
Below T_c (27ºC)	Above P_c (8 MPa or 80 bar)	Vagi, Erika et al., Fractionation of Phytocannabinoids from Industrial Hemp Residues with High-Pressure Technologies, 164 J. of Supercritical Fluids 1 (2020) (Ex. J, Canopy_000001263, at 1263, 1265, 1267-68, 1271).

This understanding of subcritical conditions extends beyond just CO_2 extractions, and to extractions using other extracts or solvents as well, as shown by the examples in Table 2:

Table 2: Extractions Using Other Solvents Deemed Subcritical Extractions Where "Both" Pressure and Temperature are Not Below their Respective Critical Points

Solvent	Solvent's T_c / P_c[7]	Extraction Temperature	Extraction Pressure	Evidence
n-propane	97ºC / 42.5 bar	Below T_c (30-60ºC)	Above P_c	Zanqui, Ana et al., Subcritical Extraction of Flaxseed Oil with N-

[7] *See* Ex. L, Canopy_000001313, at 1315.

			(8-12 MPa or 80-120 bar)	Propane: Composition and Purity, 188 Food Chem. 452 (2015) (Ex. K, Canopy_000001323, at 1323-24, 1328)
1,1,1,2-tetrafluoroethane	101ºC / 41 bar	Below T_c (40ºC)	Above P_c (12 MPa or 120 bar)	Xu, Feiyue, Development and Validation of Subcritical 1,1,1,2-Tetrafluoroethane Extraction Technique, 40 J. of Separation Science 4213 (2017) (Ex. L, Canopy_000001313, at 1314-15)

As these examples demonstrate, POSITAs over the course of at least the past 20 years, consistently understood "subcritical" conditions as encompassing pressure and temperature conditions beyond those in which "both" pressure and temperature are below their respective critical points, directly contradicting the construction GW advocates for here. *See Teva Pharm. USA, Inc. v. Sandoz, Inc*., 574 U.S. 318, 331 (2015) (recognizing district courts may "look beyond the patent's intrinsic evidence and . . . consult extrinsic evidence in order to understand, for example the background science or meaning of a term in the relevant art during the relevant time period"). GW's proposed construction ignores the plain and ordinary meaning of the disputed phrase and directly contradicts how POSITAs have used, and therefore would have understood, these terms for decades. The Court should accordingly reject GW's proposed narrowing, and construe the disputed limitation consistent with its plain and ordinary meaning.

V. CONCLUSION

For the reasons set forth above, the Court should reject GW's proposed and unjustifiably narrow claim construction and adopt plain and ordinary meaning.

Dated: August 24, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 24, 2021, a copy of the foregoing was served on all counsel of record.

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